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10/509,447

09/28/2004

Hiroki Hibino

18259

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23389

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04/02/2008

SCULLY SCOTT MURPHY & PRESSER, PC  
400 GARDEN CITY PLAZA  
SUITE 300  
GARDEN CITY, NY 11530

EXAMINER

EDWARDS, LYDIA E

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/509,447	<b>Applicant(s)</b> HIBINO ET AL.	
	<b>Examiner</b> LYDIA EDWARDS	<b>Art Unit</b> 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 January 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14 and 17-21 is/are rejected.
- 7) ☐ Claim(s) 15 and 16 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION**

***Response to Arguments***

Applicant's arguments, see amendment, filed 1/07/2008, with respect to 35 U.S.C. 112 second paragraph have been fully considered and are persuasive. The 112 2<sup>nd</sup> rejections of claims 3 and 12-14 has been withdrawn.

Applicant's arguments with respect to claims 1-18 have been considered but are moot in view of the new ground(s) of rejection.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-2, 10-11, and 18 are rejected under 35 U.S.C. 102(e) as being anticipated by Barbera-Guillem (US 2003/0040104).

Regarding Claim 1, Barbera-Guillem ('104) discloses a cell culturing system that carries in collected cells and contains them in an incoming transport container to which is attached unique identification information, transfers the transported cells to and cultures them in an intermediate container to which is attached unique identification information, and carries out the cultured cells by transferring them to an outgoing transport container to which is attached unique identification information (Paragraph 55); said system comprising an input unit that inputs identification information attached to the containers before and after transfer whenever cells are

transferred to a different container, and a memory unit that stores in memory identification information input from the input unit in mutual correlation (Paragraphs 34, 38, 42).

Regarding Claim 2, Barbera-Guillem ('104) discloses a cell culturing system according to claim 1, wherein in the case any of the identification information input from the input unit is already stored in memory, the memory unit stores other recently input identification information by adding to the existing identification information (Paragraph 34, 38).

Regarding Claim 10, Barbera-Guillem ('104) discloses a cell culturing device that cultures cells by transferring the cells to culture containers to which are attached unique identification information according to the cell culturing process; comprising, an input unit that inputs identification information attached to culture containers before and after transfer whenever cells are transferred to a different culture container, and a memory unit that stores identification information input from the input unit in mutual correlation (Paragraphs 34, 38, 42, and 55).

Regarding Claim 11, Barbera-Guillem ('104) discloses a cell culturing device further comprising a large number of culturing chambers to which are attached unique identification information; wherein, the input unit inputs identification information attached to a culture container and culturing chamber each time a culture container enters and leaves a culturing chamber, and the memory unit stores the identification information input from the input unit in mutual correlation (Paragraphs 34, 38, 42, and 55).

Regarding Claim 18, Barbera-Guillem ('104) discloses a cell culturing device wherein each set of identification information is presented by a barcode (Paragraph 34).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 3, 4, 6-9, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barbera-Guillem (US 2003/0040104) in view of Claus et al. (CA 2303243).

Regarding Claim 3, Barbera-Guillem does not explicitly state a rewriting unit.

Claus et al. ('243) discloses system further comprising a unit that is capable of rewriting previously stored identification information already stored in the memory unit (paragraphs 85 and 92).

The examiner is interpreting the method against falsification as being analogous to rewriting previously stored identification information.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Barbera-Guillem with a unit for rewriting as taught by Claus et al. in order to provide current and accurate information pertaining to the cultured cells in the automated cell management system.

Regarding Claim 4, Barbera-Guillem ('104) does not explicitly state wherein the identification information includes information relating to the steps in which each container is used

Claus et al. ('243) disclose a system wherein the identification information includes information relating to the steps in which each container is used (paragraph 45).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Barbera-Guillem with a means for including information relating to the steps in which each container is as taught by Claus et al. in order to provide current and accurate information about the cell culturing process in the automated cell management system.

Regarding Claim 6, Barbera-Guillem ('104) does not does not explicitly state a collating unit however it is inherent that the automated cell management system collates the various cell culture chambers in order to keep track of there various locations (e.g. loading and/or discarding) within the automated cell management system (Paragraph 34). Hence the automated cell management system must have a collating unit.

Claus et al. ('243) discloses a system further comprising a collating unit that collates cultured cells according to whether or not their correlation agrees with a correlation stored in the memory unit in the case the outgoing transport container identification information and the incoming transport container identification information are input as judgment information for collating cultured cells (paragraphs 45-54).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Barbera-Guillem with a collating unit as taught by Claus et al. in order to avoid errors in sample withdrawal.

Regarding Claim 7, Barbera-Guillem ('104) does not disclose a system, further comprising, in the case identification information of the outgoing transport container has been input as judgment information for collating cultured cells, a reading unit that reads identification information correlated with identification information of the outgoing transport container from the memory unit, and an output unit that outputs the read identification information, are additionally provided.

Claus et al. ('243) discloses a system, further comprising, in the case identification information of the outgoing transport container has been input as judgment information for collating cultured cells, a reading unit that reads identification information correlated with identification information of the outgoing transport container from the memory unit, and an output unit that outputs the read identification information, are additionally provided (paragraphs 35-57, 61 and 92).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Barbera-Guillem with a reading unit, memory unit and an output unit as taught by Claus et al. in order to allow each cell culture devices in the automated system to be distinguished from one another.

Regarding Claim 8, Barbera-Guillem ('104) does not explicitly state a collating device however it is inherent that the automated cell management system collates the various cell culture chambers in order to keep track of there various locations (e.g. loading and/or discarding) within the automated cell management system (Paragraph 34). Furthermore, he also does not disclose a judgment unit.

However, he does disclose carrying in collected cells by containing them in an incoming transport container to which is attached unique identification information, culturing the incoming cells by transferring to an intermediate container to which is attached unique identification information and carrying out the cultured cells by transferring them to an outgoing transport container to which is attached unique identification information, correlates and stores in memory

the identification information attached to the containers before and after transfer whenever the cells are transferred to a different container; said device comprising, an input unit that inputs incoming transport container identification information and outgoing transport container identification information as targets for collation (Paragraphs 34, 38, 42 and 55).

Claus et al. ('243) discloses a cultured cell collating device for collating incoming cultured cells with patients for use in a cell culturing system provided with a memory unit; a judgment unit that judges whether the correlation of identification information input from the input unit agrees with correlation information stored in the memory unit, and an output unit that outputs the judgment result (paragraphs 35-57, 61, 85 and 92).

The examiner is interpreting the method against falsification as being analogous to judgment of previous input identification information.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Barbera-Guillem with a judgment unit as taught by Claus et al. in order to avoid errors in sample withdrawal.

Regarding Claim 9, Barbera-Guillem ('104) does not explicitly state a collating device however it is inherent that the automated cell management system collates the various cell culture chambers in order to keep track of there various locations (e.g. loading and/or discarding) within the automated cell management system (Paragraph 34). Furthermore, he also does not explicitly state wherein judgment information for collating cultured cells in input from the identification information.

However, he does disclose carrying in collected cells by containing them in an incoming transport container to which is attached unique identification information, culturing the incoming cells by transferring to an intermediate container to which is attached unique identification information, and carrying out the cultured cells by transferring them to an outgoing transport container to which is attached unique identification information, correlates and stores in memory the identification information attached to the containers before and after transfer whenever the cells are transferred to a different container; said device comprising, an input unit that inputs identification information of the incoming transport container or outgoing transport container a reading device that reads identification information



from the memory unit that is correlated with the identification information input from the input unit, and an output unit that outputs the read identification information (Paragraphs 34, 38, 42 and 55),

Claus et al. ('243) discloses a cultured cell collating device for collating incoming cultured cells with patients for use in a cell culturing system provided with a memory unit; a judgment unit that judges whether the correlation of identification information input from the input unit agrees with correlation information stored in the memory unit, and an output unit that outputs the judgment result (paragraphs 35-57, 61, 85 and 92).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Barbera-Guillem with a judgment unit as taught by Claus et al. in order to avoid errors in sample withdrawal.

Regarding Claim 17, Barbera-Guillem ('104) discloses a cell culturing device, wherein the memory unit stores the identification information of a culture container that contains a first specimen and the identification information of a culture container that contains another specimen cultured simultaneously to that first specimen in mutual correlation (Paragraphs 34 and 38).

Claus et al. ('243) also discloses wherein the memory unit stores the identification information of a culture container that contains a first specimen and the identification information of a culture container that contains another specimen cultured simultaneously to that first specimen in mutual correlation (Paragraphs 40-45).

Claims 5, 12 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Claus et al. (CA 2303243) in view of Lerch et al (WO 97/19754).

Regarding Claim 5, Barbera-Guillem ('104) does not teach a system, wherein information on the hospital that is the origin of the incoming transport container is added to the incoming transport container.

Lerch et al. ('754) discloses a system, wherein information on the hospital that is the origin of the incoming transport container is added to the incoming transport container (page 8).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Barbera-Guillem to include hospital information on the incoming transport container as taught by Lerch et al. to provide automatic sample identification.

Regarding Claim 12, Barbera-Guillem ('104) teaches the use of sensors to control environment conditions in the biochamber (paragraph 37).

Lerch et al. ('754) discloses a sensor, in each culturing chamber, that detects internal culturing chamber information (page 5).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Barbera-Guillem to include a sensor that detects internal culturing chamber information as taught by Lerch et al. to provide adequate feedback for each cell culture device within the automated cell management system.

Regarding Claim 19, Barbera-Guillem ('104) teaches the use of sensors to control environment conditions in the biochamber of which include temperature and humidity (paragraph 37). Lerch et al. ('754) discloses a sensor, in each culturing chamber, that detects internal culturing chamber information (page 5).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Barbera-Guillem to include a sensor that detects internal culturing chamber information as taught by Lerch et al. to provide adequate feedback for each cell culture device within the automated cell management system.

Claims 13, 14, 20, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barbera-Guillem (US 2003/0040104) in view of Pfaller (US 6329195).

Regarding Claim 13, Barbera-Guillem ('104) does not explicitly disclose a medium replacement unit that replaces medium that has accumulated in a culture container but does disclose storing culture container identification information as disclosed above in claim 10.

Pfaller ('195) discloses a medium replacement unit that replaces medium that has accumulated in a culture container (Col 2, lines 47-58).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Barbera-Guillem with a medium replacement unit that replaces medium that has accumulated in a culture container as taught by Pfaller to provide adequate sample feedback during the cell culturing process.

Regarding Claim 14, Barbera-Guillem ('104) does not explicitly disclose a medium information detection unit that detects medium information but does disclose storing culture container identification information as disclosed above in claim 10.

Pfaller ('195) discloses a medium replacement unit that replaces medium that has accumulated in a culture container (Col 2, lines 47-58).

It is inherent that Pfaller contains a means for detecting medium information detection in order to maintain the desired flow properties of the culture medium.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Barbera-Guillem with a means for detecting medium information given the importance of maintaining essential nutrients and properties of the culture medium in order to support continued cell growth. Hence without accurate information on dispensing and/or properties of culture medium it is likely for the cells to die.

Regarding Claim 20, Barbera-Guillem ('104) does not explicitly disclose wherein the medium replacement information includes the date of medium replacement performed for that culture container, replaced medium, amount of growth factor and type of growth factor.

However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Barbera-Guillem with a means for tracking medium replacement information given that cell culture requires essential nutrients and properties in order to maintain and support continued cell growth. Hence without accurate information on dispensing and/or properties of culture medium it is likely for the cells to die.

Regarding Claim 21, Barbera-Guillem ('104) does not explicitly disclose wherein the medium information includes dissolved oxygen concentration and sugar content of medium supplied to a culture container. However, he does disclose a means for monitoring the dissolved oxygen concentration in the biochamber of the automated cell management system (paragraph 37).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Barbera-Guillem with a means for providing medium information specifically pertaining to the dissolved oxygen concentration and sugar content of the culture medium that is supplied, given the importance of maintaining essential nutrients and properties of the culture medium in order to support continued cell growth. Hence without accurate information on dispensing and/or properties of culture medium it is likely for the cells to die.

***Allowable Subject Matter***

Claims 15 and 16 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Regarding Claim 15, prior art fails to teach or suggest a cell culturing device comprising a cell count detection unit wherein information in correlation with the number of cells is stored.

Regarding Claim 16, prior art fails to teach or suggest a cell culturing device comprising an infection testing unit that performs infection testing on cells in a culture container wherein information in correlation with the infection testing is stored

*Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LYDIA EDWARDS whose telephone number is (571)270-3242. The examiner can normally be reached on Mon-Thur 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Walter Griffin can be reached on 571.272.1447. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lydia Edwards  
Examiner  
Art Unit 1797

LE

/Walter D. Griffin/  
Supervisory Patent Examiner, Art Unit 1797